

**REMARKS**

Claims 19-27 are pending. No new matter has been added by way of the present amendment. For instance, the present claims have been clarified such that “experimental model” language has been substituted for “ciliary muscle” language as supported by the originally filed claims. As such, the claims directed to “ciliary muscle” are clearly directed to products *per se* and not methods. Accordingly, no new matter has been added.

Additionally, Applicants respectfully submit that no new issues have been raised by the present submission which would require additional search and/or consideration on the part of the Examiner. In particular, Applicants have simply clarified the presently claimed subject matter. As such, the Examiner is not presented with the burden of additional search and/or consideration. Thus, no new issues have been raised.

In the event that the present submission does not place the application into condition for allowance, entry thereof is respectfully requested as placing the application into better form for appeal.

In view of the following remarks, Applicants respectfully request that the Examiner withdrawal all rejections and allow the currently pending claims.

Issues under 35 U.S.C. §112, second paragraph

The Examiner has rejected claims 19-24 under 35 U.S.C. §112, second paragraph for the reasons recited at pages 2-4 of the outstanding Office Action. Applicants respectfully traverse each of these rejections.

First, the Examiner has alleged that “omitted steps” relating to the actual step of inducing ciliary muscle contraction, evaluation of results, and administering medicine, have been omitted from claims 19-23. Applicants respectfully disagree. The previously pending “experimental model” claims have been modified to recite “ciliary muscle.” Although Applicants maintain that the previous “experimental model” claims were in fact product claims, it has now been clarified that claims 19-23 relate to a product *per se*. Accordingly, the recitation of steps is unnecessary.

Second, the Examiner has rejected claims 24-27 asserting that the active step correlating the results with the effects of the medicine to asthenopia are unclear. Applicants respectfully disagree. With respect to the method of claim 24, Applicants note that this claim relates only to the preparation of the ciliary muscle in a state of asthenopia. Accordingly, the “inducing” step is all that is required. Additionally, claims 25-27 recite specific steps including contacting ciliary muscle with the test medicine and measuring the effects of the medicine on a contraction of the ciliary muscle. Accordingly, this rejection is improper and should be withdrawn.

Third, the Examiner asserts that the term “substantially stable decrease” in claim 19 and 24 is a relative term. Applicants respectfully traverse. Claim 19 no longer recites this language. Further, claim 24 never recited this language. Accordingly, this rejection is moot.

In summary, Applicants respectfully submit that the present claims fully satisfy the requirements of 35 U.S.C. §112, second paragraph. Accordingly, the Examiner is respectfully requested to withdrawal each of these rejections.

Issues under 35 U.S.C. §102(b)

The Examiner has rejected claims 19-21 and 23-27 under 35 U.S.C. §102(b) as being anticipated by JP’07-133225 (herein after referred to as JP’225). Applicants respectfully traverse.

JP’225 discloses the administration of KCl to ciliary muscle showing normal contraction in the presence of a medicine so as to evaluate the counteraction of the medicine against KCl. Accordingly, in JP’225, there is only disclosure of an evaluation system for counteraction of various compounds, that is, counteraction or enhancing effects of compounds against drug inducing muscle contractions. Applicants note that this argument was submitted on January 5, 2005, and is herein incorporated by reference.

In other words, JP ‘225 discloses the treatment of ciliary muscle with KCl, a ciliary muscle contraction-inducing substance, after the treatment of ciliary muscle with compound A, a contraction-inhibitor. Thus, JP ‘225 fails to suggest or disclose ciliary muscle in a state of

asthenopia which is prepared by repeatedly contracting the ciliary muscle to show a decrease of  $50 \pm 30\%$  in the tension of muscular contraction. Further, JP '225 fails to suggest or disclose that the state of asthenopia is caused by repeatedly contracting the ciliary muscle *in vitro* with an inducer of smooth muscle contraction comprising at least one inducer selected from a chemical stimulant and an electrical stimulant. JP '225 also fails to suggest or disclose a method of preparing the present ciliary muscle or a method of using the present ciliary muscle. Accordingly, there is no anticipation based upon JP '225. Reconsideration and withdrawal of this rejection are therefore requested.

Issues under 35 U.S.C. §103(a)

The Examiner has also rejected claims 19-27 under 35 U.S.C. §103(a) as being obvious over JP'225 in view of Kitagawa and Yoshikawa. Applicants respectfully traverse this rejection.

JP '225 was discussed and distinguished above. Due to the missing elements of the present claims there can be no obviousness based on JP'225. Also, neither of the secondary references of Kitagawa or Yoshikawa '668 is able to cure the deficiencies of JP '225. Kitagawa simply discloses acetylcholine-induced contraction of smooth muscles. Yoshikawa discloses assessing the effects of drugs on smooth muscles before and after electrical stimulation. However, regardless of the disclosure of the secondary references, without the present ciliary muscle, method of preparation or method of use being disclosed by JP '225, there can be no *prima facie* case of obviousness.

Applicants would like to emphasize that even if the cited references are combined as suggested by the Examiner, it is still not possible to produce ciliary muscle in a state of asthenopia. That is, JP'225 discloses an administration of KCl to ciliary muscle showing normal contraction in presence of medicine so as to evaluate counteraction of the medicine against KCl. As such, in JP'225, only an evaluation system for counteraction of various compounds (i.e., counteraction or enhancing effect of compounds against drug inducing muscle contraction) is disclosed. Further, Kitagawa and Yoshikawa refer to contraction of smooth muscle by acetylcholine and electrostimulation. That is, only methods for inducing muscle contraction are disclosed therein.

Accordingly, by combining the cited references, one can never produce ciliary muscle in a state of asthenopia by repeating contraction of ciliary muscle, and thereby evaluate therapeutic agents against asthenopia. Accordingly, Applicants respectfully request that the Examiner withdraw this rejection.


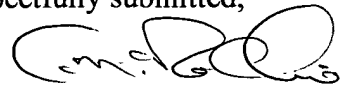
In summary, Applicants respectfully submit the present claims define subject matter which is patentable over the prior art. Accordingly, the Examiner is respectfully requested to withdrawal all rejections and allow the currently pending claims.

If the Examiner has any questions or comments, please contact Craig A. McRobbie, Registration No. 42,874 at the offices of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

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